

REMARKS

Claims 32-44 are currently pending in the present application. The Examiner has rejected all of claims 32-44 in the Official action of October 3, 2004. Claims 32-34 have been amended, and claims 32-44 are now believed allowable over the art of record for the reasons set forth below. New claims 53-56 have been added to the present application, and are believed allowable for the reasons discussed below.

In response to paragraph 2 of the detailed action, the undersigned attorney for Applicant reaffirms that all of the claims were made by the currently named joint inventors.

The Examiner rejects claims 32-43 as being "anticipated by Bartels, et al. (U.S. 4,621,632) in view of Daniell et al. (U.S. 6,050,260)." The Examiner later states: "It would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the humidity device of Bartels et al to monitor humidity by a humidity sensing means while keeping the humidity within a determined range or threshold for the well known purpose of preventing a cavity that is normally moist from drying out thereby causing inflammation causing discomfort."

It is not clear whether the Examiner is making an "anticipation" rejection, or an "obviousness" rejection, and attempts to contact the Examiner by telephone have been unsuccessful. For an anticipation rejection to be proper everything in the claim being rejected must be "within the four corners" of the reference being cited *Paeco Inc. v. Applied Moldings Inc.* 194 U.S.P.Q. (3d. Cir. 1977). Thus, if the rejection is based on anticipation, it is clearly improper, and all the claims are allowable.

If the rejection is one of obviousness based on the combination of Bartels, et al. and Daniell, for the Examiner's *prima facie* case of obviousness to withstand scrutiny, three requirements must be met: (1) There must be some suggestion or motivation to combine the references (in this case, the '632 and '260 patents), and the suggestion may come from the

references themselves or from the knowledge generally known in the art (MPEP §2143.01); (2) A reasonable expectation of success is required, and (3) the prior art reference, or references when combined, must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination, and the reasonable expectation of success must both be found in the prior art, and not be based on Applicant's disclosure. "There are three possible sources for a motivation to combine the references: The nature of the problem to be solved, the teaching of the prior art, and the knowledge of persons of ordinary skill in the art." *In Re: Rouffet*, 47 USPQ 2d 1453, (CAFC 1998).

In order to understand why the *prima facie* case of obviousness must fail, an understanding of the differences in, and development of, thoracic surgery and laproscopic surgery is desirable. Residencies in thoracic surgery began around the 1940's. Student's in such residencies spend a very small time studying the peritoneum. Therefore, students in such residencies know of the peritoneum, but have no knowledge of problems which go on in the peritoneum. Student's in thoracic residencies would not know even know the peritoneal temperature or humidity at which peritoneal cells would not do well.

As will be shown to be important hereinafter, thoracic surgeons are not familiar with problems caused by needing to place a trocar into a confined space and then inflate the confined space. Instead, thoracic surgeons are familiar with lungs, and can introduce something into the lungs through an existing outside passageway of the body, i.e., the mouth.

In complete contrast to this, laproscopic residencies appeared in approximately 1970. Students of such a residency soon learn the problems which result from operating in a confined space, i.e., the peritoneum, as opposed to the problems which thoracic surgeons would be familiar with, i.e., the lungs are a warm moist environment and adding humidity to already humid air

entering the lungs would make it only more relatively or less relatively moist.

However, laproscopic residents would learn that air is not a gas to be introduced into the abdomen. In fact, present day, government regulations say that air cannot be introduced into the abdomen because its supports combustion. It can be dangerous to the patients because of the fact that its supports combustion. Instead, laproscopic surgeons are familiar with using safe, dry, non-combustible gas such as carbon dioxide, nitric oxide, argon or helium. Therefore, the teaching of the prior art does not suggest the combination of references proposed by the Examiner.

Problems became evident in laproscopic surgery shortly after such surgery was invented. Hypothermia, shoulder pain and adhesions became familiar to the laproscopic surgeons. These problems persisted for approximately 30 years, with nobody arriving at a solution. It was not until Dr. Douglas Ott, one of the inventors in the present application, discovered what was happening. He discovered that the dry carbon dioxide, or other gasses, being used in laproscopic surgery was causing the problem. Because trocars were used to introduce carbon dioxide into the abdomen, and the major portion of the trocar was occupied by the surgical instruments being used, the gas was actually being introduced into the abdomen at a relatively high speed in the annular shaped cross-sectional area not occupied by the surgical instrument.

Further analysis by Dr. Ott drew the analogy that because of the high velocity of the gasses entering the peritoneum, something like "wind chill" was occurring. It was further determined that because of the "bone dry" nature of the gas supplied by insufflators, that heating and humidifying of the gas was needed. It was only after this analysis that the inventors arrived at the solution to the problems in the laproscopic field. The knowledge of humidifying air was known from the respiratory field for 25 years. There was a long felt need for the solution to the problems of hypothermia, shoulder pain, and adhesion, and if it would have been obvious from

the respiratory field, i.e., Bartels, et al. and Daniell, et al., these problems would have been solved long before. Therefore, the *prima facie* case also fails for the reason that there is no motivation to combine the references based on the nature of the problem to be solved. The problem simply does not exist in the respiratory field. The '632 and '260 references both deal with respiratory devices. Respiratory devices deal with supplying already moist (not dry) air (not carbon dioxide) to the outside of the body to be inhaled through a naturally occurring opening in the body such as a nasal passages or the mouth.

Lastly, medical education today is so highly specialized that thoracic surgeons, who deal with problems associated with the lungs, would not be permitted to operate on organ in the abdomen. They would not know much about the peritoneum. Further, they would not know about the temperature at which peritoneal cells do not do well. Likewise, laproscopic surgeons would not be able to operate on the lungs. Laproscopic surgeons are dealing with hypothermia, shoulder pain, adhesions and other problem in the abdomen caused by the gas being either too cold or too dry. Thus, to a laproscopic surgeon, suggesting that the '632 or '260 could solve problems in their area of expertise, would be like comparing apples to oranges. Therefore, motivation does not come from the knowledge of those skilled in the art.

In addition to there being no motivation to combine, the references themselves, if not conflicting, and if combined for the sake of argument, would not teach every element of the claimed invention. The '260 patent to Daniell states as its purpose, to vary the pressure of gasses supplied by the apparatus so that the humidity of the gasses supplied to a patient are always at the maximum of the capability of the humidifier to humidify that airflow. In reality, Daniell, et al. does not even use a humidity sensor, but an algorithm or look up table, and simply turns up the speed of his fan as the heater plate temperature increases (column 4, lines 14-19).

However, Daniell says that any suitable humidity sensor could alternatively be used. (column 4, lines 23 –24). The substitution of a humidity sensor in Daniell would do nothing to achieve the method of Applicants to set off an alarm when the humidity falls below a certain level. Danielle is only interested in increasing the humidity to maximum. Even if Daniell had a humidity sensor, the most he would do is to turn up the fan speed as the humidity rises. Again, he would never need to know the actual humidity, much less, when it falls below a certain level.

Likewise, Bartels, et al. as stated at column 8, lines 51-65, is only interested in overheating and over humidifying the air where it enters the flexible heating tube 36, and maintaining the temperature in the tube 36, through optional heater element 42, to prevent rain-out. Bartels does not even know what the humidity in his system is, as at column 9, lines 32-35, the patients breath after inspiration, in certain cases, could be very low in humidity, but that would be remedied in the next breath.

At paragraph 10, lines 20-25, the system does sound an alarm when either the proximal temperature sensed by thermistor 12, or the humidity chamber outlet temperature sensed by the thermistor 10, drops below a certain temperature. An alarm is sounded based on temperature not relative humidity, and not relative humidity falling below a certain point, as is disclosed and claimed in the present invention. Thus, Danielle, et al. and Bartels et al. are interested in regulating temperature to keep humidity at a maximum level and not to sound an alarm when humidity falls below a certain level. “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render the claims *prima facie* obvious” *In Re: Ratti* 123 USPQ 2d 349 (CCPA 1959).

It can be seen that to arrive at the method of Applicants, not only would Bartels, et al. and Daniell, et al. need to be combined, but their whole principle of operation would need to be changed, i.e., no longer operating to over humidify air or to maximize the humidity in the air, but to monitor the humidity and indicate when it has fallen below a certain level. Court's have reversed these type of rejections holding "the suggested combination of references would require a substantial reconstruction and redesign of the elements shown in the primary reference as well as the change in the basic principle under which the primary reference construction was designed to operate". *In Re: Ratti* 123 USPQ 2d 349 (CCPA 1959).

Further, with regard to Claim 32, there is nothing shown in Bartels, et al.'632 or Daniell, et al. suggesting the detecting of when the humidity of the gas is below a predetermined level.

With regard to Claim 33, there is nothing shown in Bartels, et al.'632 or Daniell, et al. '260 suggesting when the volume of liquid in a chamber requires replenishing based on the humidity of the gas in the chamber.

Referring to Claim 34, there is nothing shown in Bartels, et al.'632 or Daniell, et al. '260 suggesting the detecting of when the relative humidity is below a certain level.

In regard to Claim 35, there is nothing shown in Bartels, et al.'632 or Daniell, et al. '260 suggesting the sounding of an alarm when the liquid in the chamber requires replenishing.

With regard to Claims 36-38, there is nothing shown in Bartels, et al.'632 or Daniell, et al. '260 which suggests the recharging of the chamber in response to the alarm, or the continuing of the alarm until the chamber is replenished.

Referring to Claim 40, there is nothing shown in Bartels, et al.'632 or Daniell, et al. '260 to suggest terminating the electrical power to the heating element when it is determined that the

humidity of the gas in the chamber is below a critical level. In fact, the chamber in Daniell may run dry, and the heating element still be activated.

Further, with regard to Claims 41-42, there is nothing shown in Bartels, et al.'632 or Daniell, et al. '260 to suggest that the steps of heating and humidifying are performed substantially simultaneously within the chamber, or that the steps of sensing the humidity and temperature are performed in the flow path of the gas downstream from the steps of heating and humidifying in the chamber.

Referring to Claim 43, there is nothing shown in Bartels, et al.'632 or Daniell, et al. '260 suggesting that the chamber be immediately adjacent the patient. In fact, in both Bartels, et al.'632 and Daniell, et al. '260, the chamber is quite some distance from the patient.

In regard to Claim 44, although filtering of gases is known in the art, there is nothing shown in Bartels, et al.'632 or Daniell, et al. '260 which would suggest filtering the gas before humidifying it while detecting when the humidity of the gas falls below a predetermined level.

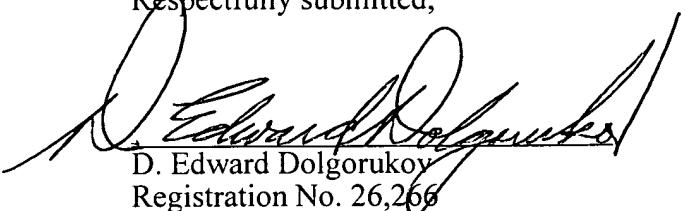
With reference to the newly presented Claims 53-56, the Examiner's attention is call to the fact that these are directed to a method of providing gas "to" a patient, instead of "into" a patient, as are Claims 32-44. Support for such claims are found in the specification at least on page 3, lines 4-9. It is noted that each of these claims though redirected, still requires, as do 32-44, detecting when the humidity of the gas being supplied to a patient is below a predetermined humidity level. This is nowhere shown in the art of record. Therefore, allowance of these claims is courteously requested.

The newly cited Perlaky (U.S. 3,582,717), Bell (U.S.6,039,696), and Warner (U.S. 4,092,625) have been considered, and are felt to be cumulative, and/or not relevant to the patentability of the present invention for the reason that they just show humidity sensing or

humidity responsive circuits, with no suggestion that they be used to condition gases for surgical procedures. In addition, Perlaky and Warner are activated when humidity rises above a certain level.

Therefore, since there is no motivation to combine, no reasonable expectation of success, the prior art does not teach or suggest all of the claim limitations, and there was a long felt need for a solution to a problem in the relevant art which was not met until the present invention was made, it respectfully maintained that the claims, as amended, are allowable over the prior art cited by the Examiner. A favorable reconsideration of the present application, and the passing of this case to issue is courteously solicited. If for any reason the claims are not allowable over the prior art, a telephone conference with the Examiner is specifically requested to place this case in condition for allowance.

Respectfully submitted,



D. Edward Dolgorukov  
Registration No. 26,266

ATTORNEYS

MARSHALL & MELHORN, LLC  
Four SeaGate, Eighth Floor  
Toledo, Ohio 43604  
(419) 249-7100  
(419) 249-7151 (Facsimile)